

82



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,070	07/14/2003	Frederick H. Sklar	B6226.1615.4370	7120

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EXAMINER

WIEKER, AMANDA FLYNN

ART UNIT PAPER NUMBER

3743

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/620,070

Applicant(s)

SKLAR ET AL.

Examiner

Amanda F. Wieker

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39, 42 and 44-50 is/are rejected.
- 7) ☒ Claim(s) 40, 41 and 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

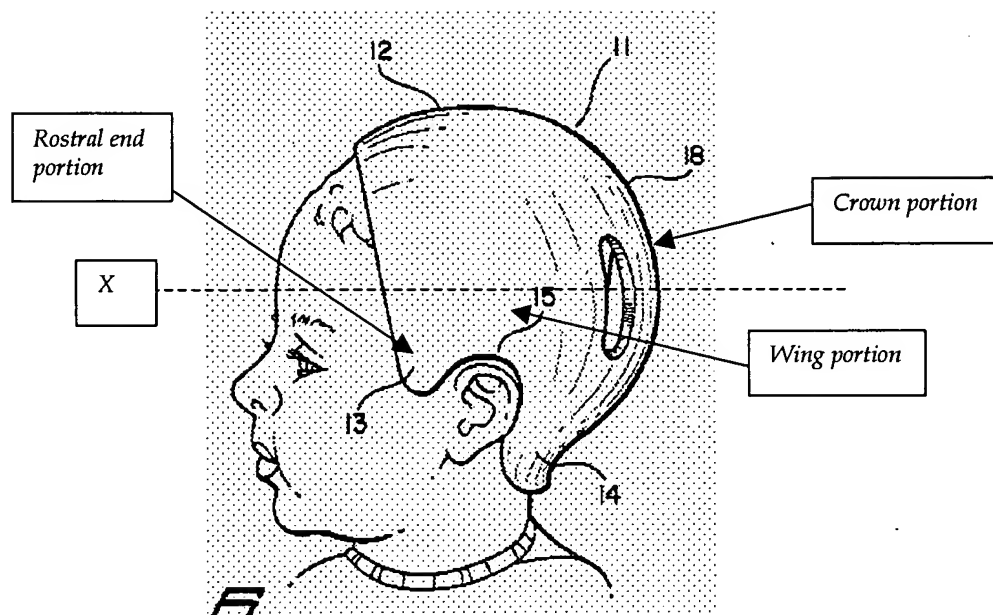
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-31, 35-39, 42 and 45-50 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 5,951,503 to Pomatto.

Pomatto discloses a cranial orthosis (11) for preventing further acquired or positional plagiocephaly in infants comprising a molded protective shell (16), helmet or headband having an interior surface that is conformed in shape to the surface curvature of a normal human infant cranium, thereby defining a cavity or pocket for receiving the head of an infant having compliant, developing head areas to be protected, the cavity being sized to provide a close, non-interfering fit of the conformed interior surface in facing relation to the developing head areas to be protected, whereby when an infant's head is received in the protective cavity, the infant's head weight forces can be spread substantially uniformly across the conformed interior surface that engages one or more of the developing head areas while the infant is resting on a sleep surface in a supine position. The protective shell (12) includes interior surfaces that are smoothly contoured and conformed in shape to the surface curvatures of the occipital, temporal and parietal areas (see Figure 6), respectively, of a human infant cranium having normal size, shape and symmetry of a healthy infant of given age and gender. The cavity is slightly oversized (at 18) relative to the head of an infant to be protected so that the infant's head can be turned from side-to-side on the sleep surface without imposing binding engagement of the

Art Unit: 3743

protective shell against the soft developing areas of the infant's head. The protective shell (12) is "loosely" fitted relative to the head of an infant to be protected so that the orthosis can be worn while the infant is resting in a supine position on a sleep surface substantially without imposing torque forces against the soft developing areas of the infant's head, while distributing the infant's head weight forces over a large segment of its cranial vault. The protective shell includes a crown portion, left and right wing portions extending bilaterally from the crown portion and rostral end portions extending from the wing portions, wherein the wing portions are dimensioned to provide at least partial overlapping coverage over the parietal areas and the temporal areas of an infant's head when it is received in the protective shell (see below). The rostral end portions are dimensioned to provide at least partial overlapping coverage over an infant's fronto-parietal and temporal areas when it is received in the protective shell, while the crown is dimensioned to provide overlapping coverage over substantially all of the occipital area of an infant's head when it is received in the protective shell. The wing and rostral portions are dimensioned to provide limited overlapping coverage whereby the upper aspects of the parietal, temporal and frontal bones are only partially covered by the appliance in the protective position, thus allowing good air circulation and heat transfer over most of the infant's head, while preventing uneven contact of the relatively soft, compliant occipital areas against the sleep surface. The shell has a U-shaped cross-section, when taken about line "X," as noted below, and has bilateral symmetry. The shell (16) comprises a unitary vacuum molding formed of plastic resin material, specifically, copolymer polypropylene. The orthosis comprises a layer of soft, flexible material (17) covering the conformed interior surface of the molded appliance. The claimed method is anticipated by the normal use of the orthosis as disclosed by Pomatto.



3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-31, 35-38, 42, and 44-50 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 4,776,324 to Clarren.

Clarren discloses a cranial orthosis for preventing positional plagiocephaly in infants comprising a protective shell (70) having an interior surface that is conformed in shape to the surface curvature of a normal human infant cranium, thereby defining a cavity for receiving the head of an infant having compliant, developing head areas to be protected, the cavity being sized to provide a close, non- interfering fit of the conformed interior surface in facing relation to the developing head areas to be protected, whereby when an infant's head is received in the protective cavity, the infant's head weight forces are spread substantially uniformly across the

Art Unit: 3743

conformed interior surface that engages one or more of the developing head areas while the infant is resting on a sleep surface in a supine position. The protective shell (70) includes interior surfaces that are smoothly contoured and conformed in shape to the surface curvatures of the occipital, temporal and parietal areas (see Figure 5), respectively, of a human infant cranium having normal size, shape and symmetry of a healthy infant of given age and gender. The cavity is slightly oversized (again, see Figure 5) relative to the head of an infant to be protected so that the infant's head can be turned from side-to-side on the sleep surface without imposing binding engagement of the protective shell against the soft developing areas of the infant's head. The protective shell (70) is loosely fitted relative to the head of an infant to be protected so that the orthosis can be worn while the infant is resting in a supine position on a sleep surface substantially without imposing torque forces against the soft developing areas of the infant's head, while distributing the infant's head weight forces over a large segment of its cranial vault. The protective shell includes a crown portion, left and right wing portions extending bilaterally from the crown portion and rostral end portions extending from the wing portions, wherein the wing portions are dimensioned to provide at least partial overlapping coverage over the parietal areas and the temporal areas of an infant's head when it is received in the protective shell. The rostral end portions are dimensioned to provide at least partial overlapping coverage over an infant's fronto-parietal and temporal areas when it is received in the protective shell, while the crown is dimensioned to provide overlapping coverage over substantially all of the occipital area of an infant's head when it is received in the protective shell. The wing and rostral portions are dimensioned to provide limited overlapping coverage whereby the upper aspects of the parietal, temporal and frontal bones are only partially covered by the appliance in the protective position, thus allowing good air circulation and heat transfer

Art Unit: 3743

over most of the infant's head, while preventing uneven contact of the relatively soft, compliant occipital areas against the sleep surface. The shell has a U-shaped cross-section, when taken through a horizontal section of the orthosis, and has bilateral symmetry. The shell (70) comprises a unitary molding formed of plastic material. The claimed method is anticipated by the normal use of the orthosis as disclosed by Clarren. Clarren further discloses s providing an inventory of protective appliances, in a variety of sizes that are indexed according to age, circumference and gender for the general infant population, measuring the circumference of an infant's head, and selecting the most closely matching protective appliance from the inventory.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pomatto in view of U.S. Patent Number 6,381,760 to Lampe et al.

Pomatto discloses the previously described cranial orthosis. Pomatto does not specify that the orthosis include a band connected to the rostral end portions and bridging across the forehead of the infant.

Lampe et al. disclose a cranial orthosis having a band of soft flexible material that bridges the forehead of a wearer, to remove sweat from the forehead. Lampe et al. specifies that the band comprise a layer of woven fabric material like open cell foam.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the orthosis disclosed by Pomatto, wherein the orthosis includes a band that bridges a wearer's forehead, as taught by Lampe et al., to absorb sweat from a wearer's brow.

Allowable Subject Matter

7. Claims 40-41 and 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

8. Applicant's arguments filed 01 February 2005 have been fully considered but they are not persuasive.

9. On page 22 of Applicant's remarks, Applicant argues that the Pomatto device is not operable to accommodate infant head growth, as newly claimed, because the orthosis is custom manufactured to fit the infant. The examiner disagrees with this argument. The Examiner directs Applicant's attention to Figure 6 of the Pomatto reference. As shown in the Figure, the Pomatto device is capable of accommodating at least a small amount of infant head growth, at least in the posterior region of the orthosis. As shown in the Figure, the posterior region of the device is spaced away from the infant's head, and such space would necessarily accommodate infant head growth in that area. It is noted that the claims do not specify the extent of head growth, which is to be accommodated by the device. The claims solely require that the device accommodate some amount of head growth. On page 23, Applicant argues that the Pomatto device is not designed to expand in size. The examiner notes that this is not a limitation of the claim.

10. On page 25, Applicant argues that the Clarren device is not operable to accommodate infant head growth because Clarren discloses a graded series of therapeutic and protective infant helmets designed for an infant of specific age and size. The examiner disagrees with this argument. The Examiner directs Applicant's attention to Figure 5 of the Clarren reference. As shown in the Figure, a space exists between the innermost layer of the Clarren device, and the infant's head. This space would necessarily accommodate at least a small amount of infant head growth, until the infant's head immediately abuts the innermost layer of the device. It is noted that the claims do not specify the extent of head growth, which is to be accommodated by the device. The claims solely require that the device accommodate some amount of head growth.

11. On page 27 of the remarks, Applicant argues that the combination of the Pomatto and Lampe et al. references is improper, because the Lampe et al. reference teaches a "binding, tight engagement" which "is not suitable for use on the soft compliant head of a newborn infant". The examiner disagrees with this argument. It is noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, the Lampe et al. reference is cited for its provision of a band of soft flexible material (i.e., a woven fabric material like open cell foam) that bridges the forehead of a wearer, to remove sweat from the forehead. The examiner believes that it would have been obvious to have provided the orthosis disclosed by Pomatto, wherein the orthosis includes a band that bridges a wearer's forehead, as taught by Lampe et al., to absorb sweat from a wearer's brow. This combination does not incorporate a "binding, tight engagement"

Art Unit: 3743

with the infant's head, as argued by Applicant. This combination solely incorporates the device disclosed by Pomatto with a flexible band of material, to remove sweat from a wearer's brow. It is also noted that the Lampe et al. reference does not disclose the orthosis as providing a "binding, tight engagement." The Lampe et al. reference discloses that the orthosis is securely retained on the person's head, as are the orthoses disclosed by Applicant, Pomatto and Clarren.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent Application Number 2003/0145384 to Stelnicki discloses a cranial orthosis having removable and stackable pads to reduce stress and aid in alignment of the infant while sleeping.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda F. Wieker whose telephone number is 703-306-4056.

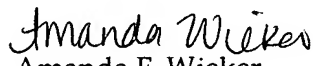
Art Unit: 3743

The examiner can normally be reached on Monday-Thursday, 8:30 - 6:00 and alternate Fridays.

The examiner's telephone number will change on 17 November 2004, to 571-272-4794.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Amanda F. Wieker
Examiner
Art Unit 3743

afw


Henry Bennett
Supervisory Patent Examiner
Group 3700